United States Patent

Donnelly

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[54] SURGICAL DRAPE

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[73] Assignee: **Kimberly-Clark Corporation, Neenah, Wis.**

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[52] **U.S. Cl.** ..... **161/39, 128/132 D, 161/164, 161/165, 161/160, 161/145, 161/190, 161/249, 161/251, 161/270**

[51] **Int. Cl.** **A61f 13/00, B32b 3/26, B32b 27/40**

[58] **Field of Search** ..... **161/190, 159, 160, 165, 249, 161/39, 156, 112, 169, 164, 145, 247, 251, 72, 270; 128/132, 132 D**

[56] **References Cited**

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3,538,912	11/1970	Becker	128/132 D
3,530,030	9/1970	Adams et al.	161/190 X
3,484,330	12/1969	Sokowski et al.	161/156 X
2,957,793	10/1960	Dickey	161/190

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[57] **ABSTRACT**

Disposable surgical drape comprising a fibrous base sheet having a primary operative area; a sheet of fluid impervious plastic film, such as polypropylene film, laminated to the base sheet in the primary operative area; and a sheet of fluid absorbent plastic foam material, such as a thin sheet of polyurethane foam, laminated to the outer surface of the film.

15 Claims, 3 Drawing Figures

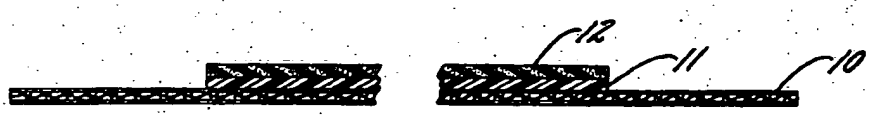


Fig. 1.

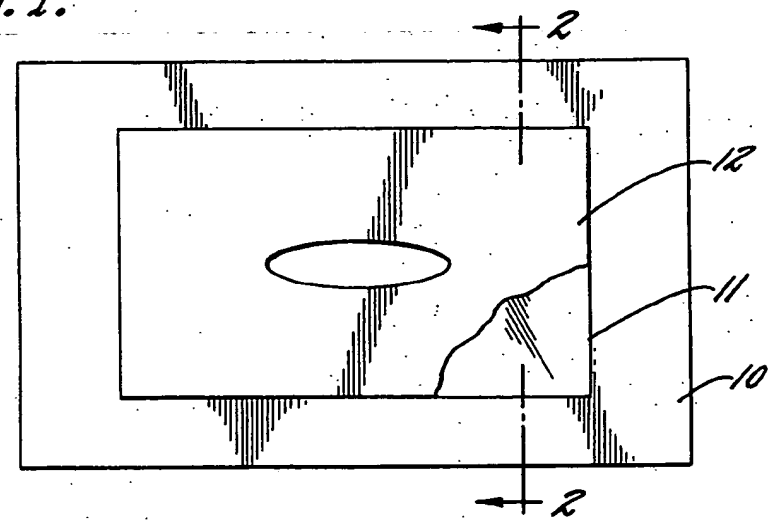
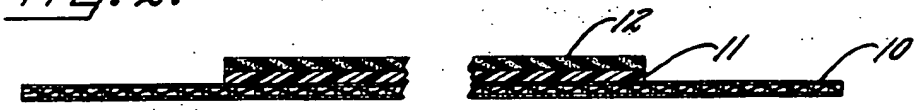


Fig. 2.



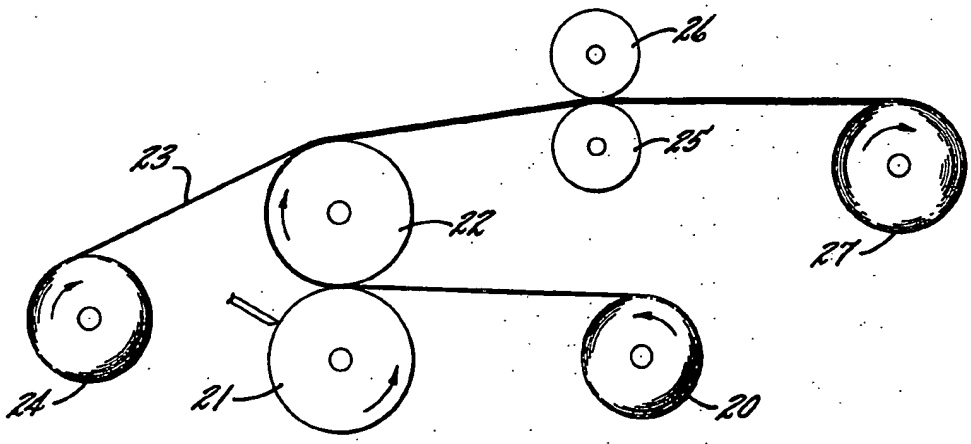


Fig. 3.

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SURGICAL DRAPE

DESCRIPTION OF THE INVENTION

The present invention relates generally to surgical drapes and, more particularly, to an improved construction for the operative areas of surgical drapes, such as the fenestration area of laparotomy sheets for example.

It is a primary object of the present invention to provide an improved surgical drape having an operative area which is strong and fluid impervious with an outside surface which is absorbent and which has a high frictional coefficient to provide good non-slip characteristics.

It is another object of the invention to provide an improved surgical drape which has a high abrasion resistance.

It is still another object of the invention to provide an improved disposable surgical drape of the foregoing type which is stable under the conditions encountered in sterilization treatments, either by steam or by ethylene oxide and the like.

A further object of the invention is to provide an improved disposable surgical drape of the type described above which prevents the passage of bacteria through the operative area of the drape.

A still further object of the invention is to provide such an improved surgical drape which has all of the aforementioned characteristics and yet can be produced at a cost sufficiently low to permit disposal of the drape after a single use.

Other objects and advantages of the invention will be apparent from the following detailed description taken in connection with the accompanying drawings in which:

FIG. 1 is a plan view of a laparotomy sheet embodying the invention;

FIG. 2 is a section taken along line 2—2 in FIG. 1; and

FIG. 3 is a schematic side elevation of a preferred system for producing the material used in the laparotomy sheet of FIGS. 1 and 2.

While the invention is susceptible of various modifications and alternative forms, certain specific embodiments thereof have been shown by way of example in the drawings which will be described in detail herein. It should be understood, however, that it is not intended to limit the invention to the particular forms disclosed, but, on the contrary, the intention is to cover all modifications, equivalents, and alternatives falling within the spirit and scope of the invention.

A wide variety of surgical drapes are in common use today as a means of preventing contamination during surgical operations. The trend today is toward the use of disposable drapes, and there has been a continuing effort to develop improved materials which will provide the desired combination of properties required for surgical drapes, and yet can be produced at a cost which is low enough to permit disposal of the drapes made therefrom after a single use. For certain types of drapes, such a variety of different properties are required that it has been difficult to develop a material which satisfies all the requirements and which can be produced economically enough to be considered disposable. For example, the material in the fenestration area of a laparotomy sheet, i.e., the area in which the operation is performed, must satisfy the following requirements;

1. The material must be strong and abrasion resistant even when exposed to the liquids and physical contact and manipulation encountered during the operation.
2. The material must be fluid impervious, both to prevent the liquids encountered during operating procedures from striking through the sheet, and to prevent the passage of bacteria through the sheet,
3. The material must have a high frictional coefficient to prevent the dislodgment of surgical instruments, supplies, and the like from the surface of the sheet during the operation.
4. The material must be stable at the conditions encountered in sterilization treatments either by stream or by ethylene oxide or the like.
5. The material must be fluid absorbent to minimize fluid run-off during the operation.

6. The material must have good draping characteristics.

All the above requirements must be satisfied in a material which can be produced at a cost low enough to render the material disposable.

In accordance with the present invention an improved disposable surgical drape which satisfies all the foregoing criteria comprises the combination of a fibrous sheet having a primary operative area, a fluid impervious flexible plastic layer laminated to the base sheet in the primary operative area, and a sheet of fluid absorbent flexible plastic foam material on the outer surface of the film. Thus, the illustrative laparotomy sheet shown in FIG. 1 includes a base sheet 10 comprising outer layers of cellulose wadding and inner layers of highly drafted fibers disposed angularly to each other. A spaced-pattern of adhesive is disposed between each fiber layer and its adjacent wadding layer with the fibers in each fiber layer partially embedded in and held by the adhesive of its adjacent adhesive layer and partially embedded in and held by the adhesive in the other adhesive layer where it extends between the fibers of its adjacent fiber layer and with a portion of the adhesive in both adhesive layers joined where the adhesive patterns are superimposed. This material is described in more detail in Sokolowski et al. U.S. Pat. No. 3,484,330, and assigned to the assignee of the present invention.

In keeping with the present invention, a sheet of fluid impervious plastic film 11 is laminated to the top surface of the base sheet 10 over the primary operative area of the sheet, which in the exemplary embodiment is the fenestration area of a laparotomy sheet. A laparotomy sheet is an elongated, generally rectangular sheet used to cover all but the operative field of a patient during thoracic or abdominal surgery, and is typically about 6 to 8 feet in length and about 3 to 6 feet in width. The film 11 may be bonded to the fibrous base sheet 10 by any suitable means, such as by means of an adhesive or by extruding the film directly on the base sheet 10. The film 11 provides a fluid impervious barrier on the top surface of the operative area of the sheet 10, so that any fluids which contact this area cannot strike through the sheet. It also prevents the transfer of bacteria through the sheet to insure sterile conditions in the operative area. The film must be capable of remaining stable under the conditions encountered in the particular treatment to which the laparotomy sheet is subjected to render it sterile, e.g., temperatures of about 270° F. for steam sterilization, or about 160° F. for sterilization by means of ethylene oxide or the like.

Examples of suitable films are polyethylene, e.g., 2-mil antistatic polyethylene film manufactured by Clopay Film Corp.; antistatic polypropylene, e.g., "Extrel II" available from Extrudo Film Corp.; polyethylene methylacrylate co-polymer film manufactured by Edison Plastics Company; and vinyl chloride films. The film should be substantially free of pinholes, and thus must generally be at least 0.15 mil thick, to provide the desired sterility barrier.

To provide a fluid absorbent outer surface on the drape, while at the same time providing a high frictional co-efficient, a sheet of fluid absorbent flexible plastic foam material 12 is laminated to the outer surface of the fluid impervious film 11. The foam material 12 may be bonded to the film 11 by any suitable means, such as by means of an adhesive, by fusing, or by extruding the film 11 directly on the foam material 12.

The absorbency of the absorbent open-cell foam 12 prevents excessive fluid runoff, and yet the absorbed fluids cannot strike through the drape because of the intermediate layer of fluid impervious film 11. The relatively high frictional coefficient of the foam material provides a substantially non-slip surface which prevents the accidental dislodgment of surgical instruments and the like. In addition, the foam 12 should have a low glare, which may be achieved by using a colored foam. Examples of suitable foams are 40 mil polyester polyurethane foam, available from Reeves Bros. or Tenneco Chemicals, Inc., having a density of 1.75 lbs./ft.^{3}, and polyether polyurethane foams. The foam thickness should generally be in the range of from about 25 mils to about 100 mils, and the absorbency of the foam sheet should be at least about 150 per-

cent and at least about 3 gm. per 4 × 4 inches sample, preferably at least 575 percent and at least 4.5 gm. per 4 × 4 inches sample. The foam sheet should also have a frictional coefficient of at least about 20°.

In order to prevent sparking due to the build-up of static electrical charges on the drape, which can be hazardous with the potentially explosive gases that are often present in the operating room, the foam 12 should also be antistatic. It is not necessary for the intermediate film 11 to be antistatic unless the specific design of the drape is such that the film 11 is exposed in a certain area, e.g., around the operative opening in the fenestration area of a laparotomy sheet.

the final drape sheet should have a Stoll abrasion of at least about 200 cycles, and preferably at least 500 cycles, both dry and wet. The outer layer of foam provides sufficient absorbency to prevent excessive fluid run-off, and yet the intermediate layer of fluid impervious film prevents the liquid from striking through the sheet, as well as providing a bacteria barrier. Moreover, the relatively high frictional coefficient of the foam provides good non-slip characteristics to prevent dislodgment of surgical instruments, supplies and the like from the surface of the sheet during the operation. Furthermore, the sheet has good draping characteristics, can be easily sterilized, and can be produced at a cost low enough to render the drape disposable.

One preferred method of producing the illustrative drape material is illustrated in FIG. 3. In this process, the plastic film is unwound from a roll 20 and passed through the nip formed by an adhesive print roll 21 and a rubber pressure roll 22 so as to apply a predetermined pattern of adhesive to one side of the plastic film. The adhesive-coated film is then passed around the rubber pressure roll 22 and laminated to the underside of a web of flexible plastic foam 23 unwound from a roll 24. In order to insure intimate engagement and bonding between the adhesive-coated side of the plastic film and the plastic foam 23, the two webs are passed through a nip formed by a rubber roll 25 and a rubber squeeze roll 26 which press the two webs together, after which the composite laminated material is wound up on a roll 27.

Suitable adhesives for use in the process illustrated in FIG. 3 are aqueous emulsion adhesives, such as "Polycryl 7F8," manufactured by Polymer Industries, Inc.; "Jedbond 83–117," manufactured by Jedco Chemical Company; and "EA–8981", manufactured by the Chemical Division of Borden Inc. The adhesive is suitably applied to the film at a loading of 2 to 10 grams per square yard and may be applied at room temperature. The pressure used to laminate the adhesive-coated film to the foam material is relatively light, and is just sufficient to make good contact between the film and foam.

After the film-foam laminate is formed, it is laminated to the base sheet 10 by any suitable technique, either manual or automatic, and either as a separate operation for each separate article or as a continuous operation similar to that illustrated for the film and foam materials in FIG. 3. When the film 11 is attached to the base sheet 10 by adhesive bonding, the same adhesives mentioned above, for use in forming the film-foam laminate, may be used.

In one example of the invention, a web of antistatic polyethylene film, 2 mils in thickness, was coated with an aqueous emulsion adhesive (Polycryl 7F8, made by Polymer Industries, Inc.) at a loading of 5 grams per square yard at room temperature, using a printing roll having a surface roughened by sandblasting. The adhesive-coated side of the film was then laminated to a web of polyester polyurethane foam, 40 mils in thickness, and the two webs were pressed together at a pressure of one pound per lineal inch. Next the film-foam laminate was laminated to a tissue-fiber base sheet of the type described in the aforementioned Sokolowski et al. U.S. Pat. No. 3,484,330, which has been treated to render it water repellant the lamination was accomplished by first coating the film side of the foam-film laminate with the same adhesive mentioned above, and then manually pressing the two materials together. The entire process was carried out at room temperature.

The resulting material was tested for abrasion resistance, absorbency, and frictional coefficient, with the following results:

Stoll Abrasion		Absorbency	Frictional Coefficient
Dry	Wet	% Gm./4"×4"	Angle (degrees)
1,100	5,000+	583 4.48	30°

The properties referred to above were determined as follows:

Abrasion Resistance:

Run on a Stoll abrasion tester with an Appleton Wire Works 54×34 mesh chrome screen, loaded with 1 lb. for 0–1,000 cycles, 2 lbs. for 1,001–1,500 cycles, 4 lbs. for 1,501–2,000 cycles and 8 lbs. for 2,001–2,500 cycles.

Absorbency: Sample 4×4 inches immersed in 30° C. water and then drained for 30 seconds. Weighed before immersion and after draining to determine gms. water absorbed, and percent weight gain.

Frictional Coefficient:

Stainless Steel surgical instrument placed on surface to be tested, which in turn is attached to an adjustable inclined plane. Angle of plane is adjusted until instrument begins to slip, which angle is the recorded frictional coefficient.

I claim:

1. An improved disposable surgical drape comprising the combination of a flexible fibrous nonwoven base sheet having a primary operative area, a flexible fluid impervious plastic film bonded to one surface of said base sheet and covering said primary operative area, and a sheet of fluid absorbent flexible open-cell plastic foam material united to the outer surface of said film, said foam material having a surface frictional coefficient of at least about 20°, said film and said foam both being stable at temperatures up to at least about 160° F. to permit sterilization of the surgical drape, the combination in said primary operative area of said base sheet of plastic film bonded thereto and plastic foam united to said film providing a fluid absorbent surface with frictional resistance to sliding movement of instruments and the like resting thereon when the drape is positioned on a patient, and a fluid barrier to prevent fluids absorbed by said foam material from striking through the drape in said primary operative area.

2. An improved surgical drape as set forth in claim 1 wherein said plastic film is selected from the group consisting of polyethylene film, polypropylene film, polyvinyl chloride film, and polyethylene methylacrylate copolymer film.

3. An improved surgical drape as set forth in claim 1 wherein said plastic foam material is selected from the group consisting of polyester polyurethane foam and polyether polyurethane foam.

4. An improved surgical drape as set forth in claim 1 wherein said sheet of plastic foam is from about 25 to about 100 mils thick.

5. An improved surgical drape as set forth in claim 1 wherein said plastic film is fused to said plastic foam material.

6. An improved surgical drape as set forth in claim 1 wherein said plastic film is adhesively bonded to said plastic foam material and to said fibrous base sheet.

7. An improved surgical drape as set forth in claim 1 wherein said plastic foam material is colored to minimize glare in said primary operative area.

8. An improved surgical drape as set forth in claim 1 wherein said drape sheet is a laparotomy sheet having an operative opening in the fenestration area thereof, and said film is laminated to said base sheet around said opening.

9. An improved surgical drape as set forth in claim 1 wherein said drape sheet has a Stoll abrasion of at least about 200 cycles dry and at least about 200 cycles wet.

10. An improved surgical drape as set forth in claim 1 wherein said sheet of foam material has an absorbency of at least about 150 percent and at least about 3 gm. per 4 × 4 inches sample.

11. In a disposible surgical drape, the combination comprising a strong flexible fibrous nonwoven base sheet having a primary operative area and an area outside said primary operative area, and a flexible film-foam laminate bonded to the top surface of the base sheet and covering said primary operative area with a film adjacent said base sheet and the surface of the foam exposed, said film-foam laminate including a layer of flexible fluid impervious plastic film united to a sheet of flexible fluid absorbent open-cell plastic foam material having a surface frictional coefficient of at least about 20°, said plastic film and said plastic foam material both being stable at temperatures up to about 160° F. to permit sterilization of the surgical drape, the combination of said nonwoven base sheet and laminate bonded thereto providing a fluid absorbent surface in said primary operative area with frictional resistance to sliding movement of instruments and the like resting thereon when the drape is positioned on a patient, and a fluid barrier to prevent fluids absorbed by said foam material from striking through the drape in said primary operative area.

12. In a disposable surgical drape, the combination as set forth in claim 11 wherein said film-foam laminate is over only said primary operative area of said base sheet, and the area outside said primary operative area comprises solely said base sheet.

13. In a disposable surgical drape, the combination as set forth in claim 12 wherein said film-foam laminate is over only said primary operative area of said base sheet providing a fluid absorbent and frictional surface, and said base sheet is water rellant such that on the surface of said base sheet outside said primary operative area water runs off rather than being absorbed.

14. A disposable surgical drape having a primary operative area with a fenestration and a drape area outside said primary operative area, said drape area comprising a strong flexible fibrous nonwoven material, and said primary operative area comprising a flexible film-foam laminate, said laminate being bonded to the top surface of the nonwoven material with the film adjacent said material and the surface of the foam exposed, said film-foam laminate including a layer of flexible fluid impervious plastic film united to a layer of flexible fluid absorbent open-cell plastic foam material and having an abrasion resistant surface with a frictional coefficient of greater than about 20°, said plastic film said plastic foam material and said nonwoven material all being stable at temperatures up to about 160° F. to permit sterilization of the surgical drape, and both layers of said laminate extending around said fenestration and to the edge of said fenestration to provide a fluid absorbent surface with frictional resistance to sliding movement of instruments and the like resting thereon when the drape is positioned on a patient, and a fluid barrier to prevent fluids absorbed by said foam material from striking through the drape around said fenestration.

15. A disposable surgical drape having a primary operative area with a fenestration and a drape area outside said primary operative area, said drape area comprising a strong flexible fibrous nonwoven material, and said primary operative area comprising a flexible film-foam laminate, said laminate being bonded to the top surface of the nonwoven material with the film adjacent said material and extending to the edge of the fenestration and the surface of the foam exposed, said film-foam laminate including a layer of flexible fluid impervious plastic film united to a layer of flexible fluid absorbent open-cell plastic foam material and having an abrasion resistant surface with a frictional coefficient of greater than about 20°, said plastic film said plastic foam material and said nonwoven material all being stable at temperatures up to about 160° F. to permit sterilization of the surgical drape, the united film and foam layers providing a laminate which is strong, has an abrasion resistant surface even when exposed to the liquids and physical contact and manipulation encountered in the primary operative area during an operation, has a fluid absorbent surface with frictional resistance to sliding movement of instruments and the like resting thereon when the drape is positioned on a patient, and provides a fluid barrier extending to the edge of the fenestration to prevent fluids absorbed by said foam material from striking through the drape around the fenestration.

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